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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/820,195

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John T. Garibotto

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09/21/2006

INSULET CORPORATION

9 Oak Park Drive

Bedford, MA 01730

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/820,195	<b>Applicant(s)</b> GARIBOTTO ET AL.	
	<b>Examiner</b> Catherine N. Witczak	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 16-22, 25-29, 31, 35-41, 49, 50, 57-59 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-22, 25-29, 31, 35-41, 49, 50, 57-59 and 69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/4/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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## DETAILED ACTION

### *Election/Restrictions*

Claims 14, 23, 24, 30, 32-34, 42-48, 51-55, 60-68, and 70-72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made in the reply filed on 8/11/2006.

Claim 56 is withdrawn from consideration because it is dependent from withdrawn claim 55.

### *Claim Objections*

Claims 10, 11, 10', and 11' are objected to because of the following informalities: different claims have the same number. For the purpose of prosecution, the first claim 10 ("sensor is subcutaneously implantable") is considered 10, and second claim 10 ("sensor is adapted to measure the physiological parameter") is considered 10a. The first claim 11 ("sensor is adapted to be positioned") is considered 11, and the second claim 11 ("sensor comprises a glucometer") is considered 11a. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-12, 16, 20, 22, 25-29, 31, 35-38, 40, 41, 49, 50, 57-59, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord et al (US 5,569,186).



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Claims: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10a, 11, 11a, 12, 20, 22, 25, 26, 27, 31, 49, 50, 69: Lord et al disclose in Figure 1 a fluid delivery system comprising: a fluid delivery device having an exit port (22), a dispenser comprising a pump for pumping insulin (14), a local processor connected to the dispenser (column 3, lines 33-42), and a local communication element connected to the local processor (Figure 1); and a remote control device having a remote processor (28) having user interface component, a remote communication element for transferring data between the local processor and remote processor (Figure 1), and a data collection assembly (26) measuring a physiologic parameter of blood glucose using a remotely deployable sensor (20) that is in electrical communication with the sensor.

Claim 10: Lord et al disclose in Figure 1 the sensor being subcutaneously implantable

Claims 28 and 29: Lord et al disclose in column 2, lines 18-21 the data collection assembly comprising a disposable element.

Claim 35: Lord et al disclose in Figure 1 the communication between the remote control device and the fluid delivery device being wireless.

Claims 36 and 37: Lord et al disclose in column 3, lines 58-61 the wireless communication using radio frequency signals.

Claims 38, 40, and 41: Lord et al disclose in column 4, lines 4-9 the remote processor being programmed to use information from the data collection assembly to calculate flow instructions.

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Claims 57 and 59: Lord et al disclose in column 3, lines 37-42 the local processor programmed to provide flow information; the local communication element connected to the local processor wirelessly (Figure 1); the remote communication unit including a receiver for receiving the flow information (column 4, lines 4-9); and the user interface including components connected to the remote processor (Figure 1).

Claim 58: Lord et al disclose in Figure 1 the fluid delivery device including a housing (14) comprising the exit port, dispenser, local processor, and local communication unit; wherein the housing is free of user output components.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 17-19, 21, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lord et al as modified by Gross et al (US 5,807,375).

Lord et al disclose the claimed invention except for the device including an audible alert activated by the data collection assembly in response to hypoglycemic conditions. Gross et al teach it is known to use an audible alarm in column 12, lines 14-20. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Lord et al with an audible alarm as taught by Gross et al, since such a modification would provide the system with an alarm system for alerting patients of potentially dangerous conditions.

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3. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lord et al as modified by Lebel et al (US 2002/0019606).


Lord et al disclose the claimed invention except for the sensor utilizing light. Lebel et al teach in paragraph 0117 that it is known to use a light-utilizing sensor to detect physiological parameters. It would be been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Lord et al with a light utilizing sensor, since such a modification would provide with a means for detecting the level of a desired physiological parameter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NICHOLAS D. LUCCHESI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700